IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NATERA, INC.,)
Plaintiff,))
v.) C.A. No. 20-125 (LPS)) (CONSOLIDATED)
ARCHERDX, INC., ARCHERDX, LLC and INVITAE CORP.,) REDACTED - PUBLIC VERSION
Defendants.)

NATERA, INC.'S LETTER BRIEF IN OPPOSITION OF DEFENDANTS' OCTOBER 12, 2021 DISCOVERY DISPUTE LETTER

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Dear Judge Stark:

Plaintiff Natera, Inc. ("Natera") submits this response to Defendants' ArcherDX, Inc., ArcherDX, LLC and Invitae Corp. ("Defendants") October 12, 2021 Renewed Discovery Dispute Letter (D.I. 357).

I. INTERROGATORY NO. 24

As explained in Natera's letter in opposition to Defendants' September 29 discovery letter, Defendants seek to turn their burden to show a lack of adequate written description on its head by requesting from the party without the burden not simply where each claim draws written description support (which would subvert the burden), but where it is present in a specific embodiment (which further distorts the law). D.I. 344. It is black letter law that the written "description requirement does not demand any particular form of disclosure." Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) (citing Carnegie Mellon Univ. v. Hoffman-La Roche Inc., 541 F.3d 1115, 1122 (Fed. Cir. 2008)). The law is also "clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement." Id. at 1352. Indeed, "the critical inquiry is whether the patentee has provided a description that in a definite way identifies the claimed invention in sufficient detail that a person of ordinary skill would understand the inventor was in possession of it." Alcon Research, Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1190-91 (Fed. Cir. 2014). Because "the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before...it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention..." LizardTech. Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005).

Notably, even Defendants' own final invalidity contentions do not disclose claim-by-claim or element-by-element, their written description defense for each patent. Despite Natera's consistent position that Defendants have not met their burden of showing why and how the asserted patents do not teach the claimed inventions, Natera agreed to – and did – sufficiently supplement its response. Contrary to Defendants' arguments, Natera identified numerous single embodiments in the specification that disclose each element of the asserted claims that are clearly reflected by the pin-cites to the specification in its supplemental response. Ex. 1 at 35-37. Moreover, it is entirely consistent with Natera's response to Defendants' request for admission that the specification discloses at least a single embodiment that includes all claim limitations.

Defendants' primary complaint of numerous cites seems to be due to the wealth of embodiments disclosed in the specification as the specification specifically describes multiple embodiments, as Defendants' letter plainly concedes. For example, claim 1 of the asserted '814 Patent states as an element: "performing a first PCR to simultaneously amplify at least 10 target loci using a universal primer and at least 10 target-specific primers in a single reaction volume." The specification discloses language such as:

In various <u>embodiments</u>, the method includes ligating <u>a universal primer binding</u> site to the DNA molecules in the sample; amplifying the ligated DNA molecules using e.g. at least

100 (e.g., at least 300 or 1,000) specific primers and a universal primer to produce a first set of amplified products; and amplifying the first set of amplified products using e.g. at least 100 (e.g., at least 300 or 1,000) pairs of specific primers to produce a second set of amplified products. In various embodiments, at least 500; 750; 1,000; 2,000; 5,000; 7,500; 10,000; 15,000; 19,000; 20,000; 25,000; 27,000; 28,000; 30,000; 40,000; 50,000; 75,000; or 100,000 different primer pairs are used. In various embodiments, at least 500; 750; 1,000; 2,000; 5,000; 7,500; 10,000; 15,000; 19,000; 20,000; 25,000; 27,000; 28,000; 30,000; 40,000; 50,000; 75,000; or 100,000 different target loci are amplified.

Ex. 2, '814 Patent at 15:47-62 (emphasis added). All of the forgoing describes multiple embodiments that plainly disclose the claim limitation exceeding at least 10 target specific primers, at least 10 target specific loci, and a universal primer. The specification is rife with such rich and fulsome description of embodiments, rendering the long list of cites wholly-appropriate. Indeed, Defendants' letter brief admits as such, acknowledging there are "multiple embodiments across the 200-page specification." Defendants are simply trying to strip the specification of the wealth of multiple embodiments disclosed and cited, contrary to *Ariad's* black letter law requirement that written description "does not demand any particular form of disclosure." *Ariad Pharms.*, 598 F.3d at 1352.

Defendants demand Natera provide a claim-by-claim, element-by-element response although Natera's response already sufficiently identifies single embodiments in the specification that disclose each element of the asserted claims. But this demand stands in contradiction to their own refusal to provide the same level of response to Natera's Interrogatory No. 5, which seeks Defendants' non-infringement positions on a claim-by-claim, element-by-element basis. Ex. 3 at 8-16. "The adequacy of all interrogatory answers shall be judged by the level of detail each party provides; i.e., the more detail a party provides, the more detail a party shall receive." D.I. 60 at 5. Defendants cannot have it both ways. Natera also refers the Court to Natera's letter brief in support of its motion to compel supplementation of Interrogatory No. 5 to provide the factual and legal basis for their non-infringement contentions on a claim-by-claim, element-by-element basis. D.I. 358.

Respectfully,

/s/Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF/lo Attachments

cc: Clerk of the Court (via CM/ECF)

All Counsel of Record (via CM/ECF and e-mail)